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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/062,548	02/05/2002	David W. LaFleur	PZ024P1C1	3544

22195 7590 07/28/2003

HUMAN GENOME SCIENCES INC  
9410 KEY WEST AVENUE  
ROCKVILLE, MD 20850

EXAMINER

KIM, YOUNG J

ART UNIT	PAPER NUMBER
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1637

8

DATE MAILED: 07/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/062,548

Applicant(s)

LAFLEUR ET AL.

Examiner

Young J. Kim

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 11, 12, 17, 19, 20 and 24-55 is/are pending in the application.
- 4a) Of the above claim(s) 17, 19 and 20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11, 12 and 24-55 is/are rejected.
- 7) ☒ Claim(s) 11 and 12 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1, 8.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: *Sequence Homology Search*.

## **DETAILED ACTION**

### ***Preliminary Remark***

The Office acknowledges the cancellation of claims 1-10, 13-16, 18, and 21-23, cancelled without prejudice or disclaimer, and the addition of claims 24-55.

### ***Election/Restrictions***

Applicant's election with traverse of Group II, claims 11, 12, 14-16, 20, and newly added claims 24-55 and clone ID HHEPU32 encoding the polypeptide of SEQ ID NO: 97, in Paper No. 7 is acknowledged. The traversal is on the ground(s) that a "serious search burden" as set forth in MPEP 803 has not been established. Applicants argue that a single search in polynucleotide will return useful information about its encoded polypeptide and polypeptide provides useful information about its antibody. This is not found persuasive because the Office follows a different protocol when searching sequences. A polynucleotide sequence is searched only in databases (commercial, issued-patent, and pending-patent), returning only polynucleotide sequences as results. Similarly, a polypeptide sequence query results only in matched polypeptide sequences. Additionally, for each claimed SEQ ID Number, the Office must perform a sequence search, for each SEQ ID Number, on a commercial database (which includes multiple databases), PTO in-house database, and the issued-patent database. Therefore, searching polynucleotides and polypeptides combined, therefore multiple SEQ ID Numbers, in each of these databases would lead to an enormous search burden on the Office.

With regard to Applicants' argument drawn to the methods of using the elected polypeptide, such argument is not found persuasive because while searches performed on the

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polypeptide would return information only about the polypeptide itself. Therefore, in order to search the method using the polypeptide as a diagnostic, therapeutic agents, etc, would require searches in the state of the art, enablement of the art, all of which would not be coextensive and would become an added search burden.

The requirement is still deemed proper and is therefore made FINAL.

Claims 17, 18, and 20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 7.

#### ***Claim Objections***

Claims 11 and 12 are objected to because of the following informalities: Claim 11 and 12 do not recite the elected invention, that is, the elected SEQ ID Number 97 as the polypeptide. Amending the claims to explicitly recite the elected SEQ ID Number would overcome this objection. Additionally, Applicants are advised to amend the ATCC Deposit ID which corresponds to the elected polypeptide SEQ ID Number – i.e., encoding the polypeptide. Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 11, 12, and 46-55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 11 and 12 are indefinite for the recitation of the phrase, "SEQ ID NO: Y or the encoded sequence included in ATCC Deposit No:Z," because it is unclear whether the ATCC Deposit No:Z encodes the isolated polypeptide of SEQ ID NO: Y, or it is drawn to another encoded sequence. Amending the phrase to recite, "SEQ ID NO: Y or **its encoding** sequence included in ATCC Deposit No:Z," would overcome this rejection.

Claim 12 is indefinite for the recitation of the phrase, "comprises sequential amino acid deletions from either C-terminus or the N-terminus," because the claim is unclear in how many amino acid deletions are embraced by the term, "sequential," rendering the claim vague in its metes and bounds.

Claims 46-55 are indefinite for the recitation of the phrase, "consisting of at least," because it is unclear how many amino acid sequences are considered to be within the phrase, "consisting of at least," versus "comprising." For the purpose of prosecution, the phrase is interpreted as meaning "comprising at least."

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an

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international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 11, 12, and 24-55 are rejected under 35 U.S.C. 102(e) as being anticipated by Baker et al. (US 2003/0073129 A1, published April 17, 2003, priority September 1, 1998).

The instant rejection is predicated on the fact that the instant application is a continuation of US 09/369,247, filed on August 5, 1999, which is a **continuation-in-part** of PCT/US99/02293, filed on February 4, 1999. Because it is not determinable whether the claimed SEQ ID NO: 97 was present or absent in the PCT application and its parent US provisional applications, absent evidence to the contrary, the effective filing date of the instant application is determined to be that of '247 application (August 5, 1999), from which the instant application is a continuation of.

Additionally, due to the sheer volume of pages of the cited publication, only the pertinent pages of the reference is being provided, namely – front page of the patent, sections of the disclosure with regard to the matching polypeptide, and the matching polypeptide sequence.

Baker et al. disclose an isolated polypeptide which has a 100% overall homology to that of the claimed polypeptide of SEQ ID NO: 97 and its encoding cDNA deposit ID: DNA76531-1701 ([2347], Homology Search Report, and attached sequence from <http://seqdata.uspto.gov>) (claim limitation 11, 24-26, 29, 30, 32, 35-37, 40-42, 45-47, 50-52, and 55). The polypeptide lacking the N-terminus/C-terminus as well as that which lacks the starting methionine is also disclosed [2354; claim limitation 12 and 31]. An embodiment of the polypeptide is drawn to that which comprises a heterologous sequence (Abstract, claim limitation 27, 33, 38, 43, 48, and 53). Finally, a composition comprising the polypeptide and an acceptable carrier is also taught [2365, claim limitation 28, 34, 39, 44, 49, and 54).

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Therefore, Baker et al. anticipate the invention as claimed.

***Conclusion***

No claims are allowed.


The polypeptide of SEQ ID NO: 97 is disclosed as being primarily expressed (or differentially expressed) in testes tumor tissues (specification page 77, line 5), rendering the claimed polypeptide useful as a diagnostic, thereby satisfying the utility requirement under 35 U.S.C. 101. The sequence listing evidences a full-length of the claimed polypeptide, thereby satisfying the written description requirement under 35 U.S.C. 112, 1<sup>st</sup> paragraph.

***Inquiries***

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (703) 308-9348. The Examiner can normally be reached from 8:30 a.m. to 7:00 p.m. Monday through Thursday. If attempts to reach the Examiner by telephone are unsuccessful, the Primary Examiner in charge of the prosecution, Dr. Kenneth Horlick, can be reached at (703)-308-3905. If the attempts to reach the above Examiners are unsuccessful, the Examiner's supervisor, Gary Benzion, can be reached at (703) 308-1119. Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. The Fax number is (703) 746-3172. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Young J. Kim

7/24/03

  
JEFFREY SIEW  
PRIMARY EXAMINER

7/27/03